FEB 1 5 2001

K003915

SUMMARY OF SAFETY AND EFFECTIVENESS

December 1, 2000

Trade Name: Accufuser; Accufuser plus

Common Name: Elastomeric Infusion Pump Kit

Classification Name: Pump, Infusion, Elastomeric

Classification Panel: General Hospital and Personal Use Device

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq.
Managing Director

HELP Technologies
24312 Armada Dr.
Dana Point, CA 92629
Telephone: 949.240.1290
Fax: 949.240.3460

1.0 DESCRIPTION OF THE ACCUFUSER PRODUCT

1.1 The Accufuser pump (Continuous type Silicone Balloon)

1.1.1 The pump provides continuous fluid delivery with attached, fixed rate administration set.

1.1.2 The pumps are supplied as fixed flow rates.

1.1.3 A silicone balloon is used as both the fluid reservoir of the device and the pressure (energy) source.

1.2 The Accufuser plus pump is the Accufuser with the addition of a Patient Medication Control Module (PCM)

1.2.1 Patient Medication Control Module allows the patient to administer a bolus of fixed volume with a fixed lockout (re-fill) time.

1.2.2 The pump is a disposable device intended for single patient use.

1.2.3 The pump is suitable for use as an ambulatory device and is intended for use in the hospital, home environment or alternative care sites.

1.2.4 The Accufuser and the Accufuser plus pumps are substantially similar to the I-Flow Homepump (Eclipse) C-Series, the Baxter Infusor and Intermate, the McKinley OutBound, Go Medical Elastomeric pump and the B Braun spring pump (used in the Sgarlato pain kit).

2.0 THE ACCUFUSER/ACCUFUSER PLUS PUMP AND ITS PREDICATE DEVICES ARE INTENDED:

2.1 for general infusion use. Routes of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural and into the intra-operative (soft tissue / body cavity) site.

2.2 general infusion use includes pain management for pre-operative, perioperative and postoperative surgery.

2.2.1 The predicate pumps (and the pumps included with the Baxter Pain Pump, I-Flow PainBuster Infusion Kit and the Sgarlato Pain Control Infusion Pump (PCIP) have the same intended use as the device under review:

2.2.2 The predicate Homepump C-Series is intended for general infusion use, including chemotherapy and pain management. The routes of administration include intravenous, intra-arterial, subcutaneous and epidural.

2.2.3 The predicate McKinley Outbound Syringe Infuser is indicated for intravenous, intra-arterial, subcutaneous, to

2.2.3 The predicate McKinley Outbound Syringe Infuser is indicated for intravenous, intra-arterial, subcutaneous, to provide continuous infusion of a local anesthetic directly into the intraoperative site for general surgery for postoperative pain management and epidural infusion of medications or fluids requiring continuous delivery at controlled infusion rates.

2.3 Device Descriptions

2.3.1 Specifications

2.3.1.1 The Accufuser and the Accufuser plus have fill volumes and flow rates substantially similar to the pumps of the I-Flow PainBuster (Homepump Eclipse C-Series), the B Braun spring pump included in the Sgarlato PCIP, the Baxter Infusor and Intermate, and the vacuum Outbound infusion pumps (found in the Stryker pain kit), see Table 1.

2.3.2 Flow Control

2.3.2.1 The Accufuser and Accufuser plus pumps and the identified predicate device use either a glass orifice or PVC tubing to control the flow rate.

2.3.3 Materials

2.3.3.1 All fluid path materials of the Accufuser pumps are in conformance with ISO 10993 Part 1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 5 2001

Mr. Robert J. Bard
Managing Director
HELP Technologies
24312 Armada Drive
Dana Point, California 92629

Re: K003915
Trade Name: Accufuser and Accufuser plus
Regulatory Class: II
Product Code: MEB
Dated: December 4, 2000
Received: December 19, 2000

Dear Mr. Bard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003915

Device Name: Accufuser and Accufuser plus

Indications for Use:

The Accufuser and Accufuser plus pumps are intended for general infusion use. Route of infusion include intravenous, percutaneous, subcutaneous, intra-arterial and epidural and into the intraoperative (soft tissue / body cavity) site. The Accufuser plus is also intended for patient controlled infusion using the integrated bolus button. General infusion uses include pain management for pre-operative, perioperative and postoperative surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUED ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucuzzella

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003915

Prescription Use _____ OR Over-The-Counter Use _
(Per 21 CFR 801.109)